



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

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February 8, 2005

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 05-14

Donald L. Smyth, President
R-Garden, Inc., and
Rose Creek Health Products, Inc.
14 Enzyme Lane
Kettle Falls, Washington 99141

WARNING LETTER

Dear Mr. Smyth:

The Food and Drug Administration (FDA) inspected your firms located at 14 Enzyme Lane, Kettle Falls, Washington, on October 26-28, 2004. During the inspection our investigator collected information, including product labeling and copies of scientific research and studies, that you provided to substantiate the claims made for your "Vitamin O" products. In addition, we reviewed your websites at the following Internet addresses: <http://www.rgarden.com>, <http://www.rgarden.net>, and <http://www.rgarden10.net>. Our review of the information collected during the inspection and your websites found numerous violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet web site at <http://www.fda.gov>.

Under section 201(g)(1)(B) of the Act (21 U.S.C. 321(g)(1)(B)), articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs. Based on claims that appear on your website for R-Garden, Inc., including claims in the form of testimonials, and in literature you distribute in each product shipment for both R-Garden, Inc., and Rose Creek Health Products, Inc., we have determined that your "Vitamin O" products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B). The therapeutic claims on your websites and in your promotional materials establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

Examples of some of the claims observed in your health newsletters, which are distributed with each individual shipment of R-Garden, Inc., and Rose Creek Health Products, Inc. "Vitamin O" products, include:

- October 2004: "I have congestive heart failure. ... I was so weak someone had to help me walk. After taking 'Vitamin O' for three months, I can walk. I no longer take heart pills or pain pills."

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- November 2004: "What a difference 'Vitamin O' has made in my life. I started taking it about 3 years ago when I came down with COPD [chronic obstructive pulmonary disease]. I also was getting chronic bronchitis and pneumonia all the time. ... The doctor once said to me - whatever you're doing keep doing it. I breathe very easily now."

Examples of some of the claims observed in product descriptions on your website for R-Garden, Inc., "Vitamin O" include:

- "*Vitamin O* for the skin...Cuts & Burns...Pain...Etc."
- "So many people have written in telling us how [Vitamin O] has clear[ed] ear and skin infections ..., reliev[ed] allergies and shorten[ed] the misery of colds."

Examples of some of the claims observed in testimonials for R-Garden, Inc., "Vitamin O" from your websites include:

- "Cuts on my hands...take a long time to heal. 'Vitamin O' clears them in hours and they heal in a couple of days. Gargling with a few drops stops gum infection and pain. ...Took a skin cancer off my nose."
- "At every step, the "electrically-activated" oxygen killed cold viruses on contact, reduced inflamed nasal mucosa, removed nasal congestion, stopped postnasal drip, healed a sore throat, AND (after I drank some also) permitted my lungs to return to their normal operations. ... Dr. John Heinerman from Oxygen Matters".
- "I have suffered from intermittent outbreaks of genital herpes for 30 years. ... Unbelievably, the 'Vitamin O' caused a complete disappearance of the sore in around 24 hours. The pain and itch left within the first few hours."
- "I have had chronic bronchitis since 1962 (36 years!). I coughed most of the time. Since being on the 'Vitamin O', I no longer cough."
- "I have been taking 'Vitamin O' for about two years now. It helps keep Candida under control."
- "I have had chronic sinusitis for many years. I have been on every antibiotic on the market, but they only gave temporary relief. Then I discovered 'Vitamin O' and have found it to cure my sinusitis each time within 48 hours."
- "My son had as severe head injury... I use 'Vitamin O' for his frequent seizures. I've learned the 'Vitamin O' has helped to lessen the amount of seizures, and a few months ago found that if I gave him 20 drops of 'Vitamin O' at the first signs of a seizure he doesn't have a seizure at all."
- "Four years ago I suffered a heart attack brought on by severe asthma. ... I heard of 'Vitamin O'... Now after two bottles ... [t]he chest pains are gone. The asthma is now a rare occurrence."
- "I have fibromyalgia 'Vitamin O' ... has lessened my pain."
- "I have had every form of bronchial problems. After using 'Vitamin O,' I am off antibiotics and inhalers."

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- "[A]lthough I have been taking "Vitamin O" a short time it has already helped me so much. I have arthritis, chronic fatigue, and Hepatitis C. ... I know 'Vitamin O' is not said to be a cure-all. But it sure is the next best thing..."

Examples of some of the claims observed in testimonials from the booklet "Fruits of R-Garden Internationale Testimonials," which is distributed with each individual shipment of R-Garden, Inc., and Rose Creek Health Products, Inc. "Vitamin O" products, include:

- #118: "Lung Cancer... I had a diagnosis of cancer in both lungs. ... My breath and legs would give out.... Three days after starting the 'Vitamin O' I threw my cane away. ...In December the X-rays showed that both tumors were getting smaller."
- #144: "I was disabled last October with lung cancer. ... I read about 'Vitamin O' and decided to get some. ...My legs don't give out anymore; my breathing is 25% better. My blood pressure also dropped."
- #145: "'Vitamin O' Helps Control Angina ... I have heart disease. ... 'Vitamin O' has made a large difference in controlling my angina. I am able to reduce it or even prevent it. I am recommending 'Vitamin O' to anyone suffering from respiratory or cardiovascular problems."
- #156: "Cataract Going Away ... I was developing a cataract in my left eye. ... Imagine my amazement when the second day of using a drop twice daily I could tell a difference. I have now finished my bottle and my problem is almost totally gone."

Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 U.S.C. 321(p)]. Under section 505 of the Act (21 U.S.C. 355), a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). Your Vitamin O products are also misbranded under section 502(f)(1) of the Act, in that the labeling does not bear adequate directions for use.

R-Garden, Inc. "Vitamin O Spray," and Rose Creek Health Products, Inc., "Vitamin O Spray Stabilized Oxygen Molecules," although labeled as dietary supplements, are intended for use as topical sprays for use on the skin and in the ears and nose. Under section 201(ff)(2)(A)(i) of the Act [21 U.S.C. 321(ff)(2)(A)], the term "dietary supplement" is defined as, among other things, a product "intended for ingestion." Products that are intended to be used topically or introduced into the body other than through ingestion are not dietary supplements because they are not "intended for ingestion." In addition to the disease claims stated above that cause these products to be drugs, they also appear to be drugs under 21 U.S.C. 321(g)(1)(C) because they are articles (other than food) intended to affect the structure or function of the body. Examples of claims that your products affect the structure or function of the body are listed in the following section.

Substantiation

Even if your Vitamin O products that are intended for ingestion did not bear claims that cause them to be drugs, as dietary supplements they would violate other provisions of the Act. Your

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R-Garden, Inc. and Rose Creek Health Products, Inc., "Vitamin O" products are misbranded under sections 403(r)(6)(B) and 403(a)(1) of the Act [21 U.S.C. 343(r)(6)(B) and 343(a)(1)] because the products' labeling includes unsubstantiated claims. Under the Act, dietary supplements may be legally marketed with claims to affect the structure or function of the body (structure/function claims), if certain requirements are met [21 U.S.C. 343(r)(6); 21 C.F.R. 101.93(f)]. The manufacturer of a dietary supplement containing a "structure/function" claim in the product's labeling must have substantiation that the claim is truthful and not misleading [see 21 U.S.C. 343(r)(6)(B)].

Product labels for R-Garden, Inc. "Stabilized Vitamin O" and "Vitamin O" state "[i]n double blind clinical studies involving blood gas analysis, Vitamin O has been shown to significantly increase blood oxygen levels." In the product brochure "R-Garden Products for the Garden Within Us", which is distributed with all R-Garden, Inc. and Rose Creek Health Products, Inc Vitamin O product shipments, it states "[i]n a 6-month double-blind study, those taking Vitamin O showed a 17% to 32% increase in arterial blood oxygen! In oral interviews conducted during this study, research participants reported greater youthfulness, improved mobility, better circulation, sharper mental clarity, enhanced lung and heart function, and increased physical energy."

We have reviewed these claims, along with the substantiation package you provided during the inspection, and concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of section 403(a)(1) and 403(r)(6)(B) of the Act [21 U.S.C. 343(r)(6)(B) and 343(a)(1)].

Labeling

The product R-Garden, Inc. "Stabilized Vitamin O," 16 Fl. Oz., is misbranded under sections 403(i)(1) and 403(s)(2)(B) of the Act [21 U.S.C. 343(i)(1) and 343(s)(2)(B)] because the label fails to identify the product with the term "dietary supplement" (or an appropriate alternative authorized by regulation) as part of the statement of identity, on the principal display panel, as specified in 21 CFR 101.3(d) and (g).

Your "Vitamin O" products that are intended for ingestion are further misbranded under Section 403(q)(5)(F) of the Act in that the nutrition information in their labeling fails to meet the requirements of 21 CFR 101.36.

The following are examples:

- R-Garden, Inc., "Stabilized Vitamin O" and "Vitamin O," and Rose Creek Health Products, Inc., "Vitamin O Stabilized Oxygen Molecules" product labels do not comply with 21 C.F.R. 101.36(c)(1) in that they do not include the quantity or percent daily value (either a percentage of the Reference Daily Intake (RDI) or Daily Reference Value (DRV)) for each dietary ingredient in the proprietary blend for which a declaration of quantity or percent daily value is required under 21 CFR 101.36(b)(2) (for instance, sodium). Further, these product labels do not comply with the requirement to disclose that no daily value has been

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established for the proprietary blend. Under 21 C.F.R. 101.36(c)(3), the statement "Daily Value not established" must appear in a footnote at the bottom of the Supplement Facts panel (i.e., the nutrition information section of the label), and a symbol (e.g., an asterisk) referring readers to the footnote is required to appear on the same line as the term "Proprietary Blend" under the heading "% Daily Value," if present, or immediately following the quantitative amount by weight of the proprietary blend.

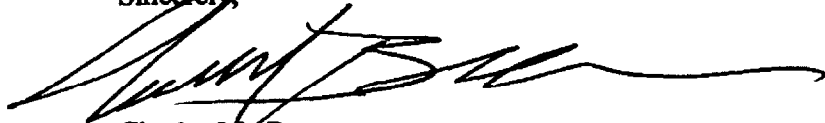
- R-Garden, Inc. "Stabilized Vitamin O" and "Vitamin O," and Rose Creek Health Products, Inc. "Vitamin O Stabilized Oxygen Molecules" product labels do not list the subheading, under Serving Size, of "Servings Per Container," or the number of servings per container, as required by 21 CFR 101.36(b)(1)(ii).
- R-Garden, Inc., "Stabilized Vitamin O" and "Vitamin O," and Rose Creek Health Products, Inc., "Vitamin O Stabilized Oxygen Molecules" product labels do not specify the quantitative amount by weight of the proprietary blend of ingredients declared on the label, as required by 21 CFR 101.36(c)(3).

This letter is not intended to be an all inclusive review of your products and labeling. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to immediately cease distribution of your violative products could result in enforcement action by FDA without further notice. The Act provides for the seizure of illegal products, injunctions against the manufacturers and/or distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct these violations, including any steps taken with respect to violative products currently in the marketplace, and an explanation of each step taken to assure that violations do not recur. Your reply should be sent to the Food and Drug Administration, Attention: Lisa Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,



Charles M. Breen
District Director

cc: WSDA with disclosure statement

cc: Federal Trade Commission
Northwest Region
Federal Building
915 Second Avenue, Suite 2896
Seattle, Washington 98174